

## **REMARKS**

Claims 1-88 and 90-99 are pending in the application. Claims 3-4, 76-77, 83-88 and 98-99 have been amended in a non-limiting manner to improve the form of the claims. No new matter has been added.

Examiners Graffeo and Low are thanked for the courtesy of the telephone interview with Applicants' below signed attorney on February 8, 2006. In addition to the information contained in the Examiner's Interview Summary, the following is noted. While all pending claims were discussed generally, claims 1, 70, 81 and 86 were discussed more specifically. The only prior art specifically discussed was U.S. Patent Application Publication No. 2005/0013902 (Pearce) and U.S. Patent No. 4,971,806 (Cherukuri). The general thrust of the principal argument presented was that Pearce does not constitute prior art and the earlier-filed Pearce provisional applications do not disclose a pullulan-free edible film as called for by many of the claims. The remarks below repeat the arguments presented during the interview. One other item discussed in the interview was that it appeared that claim 70 was inadvertently included in the list of claims rejected over Cherukuri. As noted in the Examiner's Interview Summary, no agreement was reached except that the rejection of claim 70 over Cherukuri was a typographical error.

### **Claim Objection**

Claims 3-8 were objected to in the outstanding Office Action. This objection is traversed as to claims 5-8, and is overcome in view of the amendments of claims 3-4. An article ("the") has been added before "edible film" in claims 3 and 4. However "the" was already present in the previously amended form of claims 5-8.

### **Claim Rejections - 35 U.S.C. §103(a)**

Claims 1-22, 24-88 and 90-99 were rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Application Publication No. 2005/0013902 (Pearce) in view of the article by Al-Zuhair et al in Pharmacological Research, Vol. 34, No.1/2, 1996 (Al-Zuhair). This rejection is respectfully traversed.

Claim 1 requires of a pullulan-free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising cardamom oil. This composition is not disclosed in the cited art, nor would it have been obvious in view of the cited references taken alone or in combination.

Similarly, claim 42 is directed to a method of oral cleansing using a pullulan-free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising cardamom oil.

Claim 62 is directed to a method of making a pullulan-free edible film composition comprising an effective amount of a film forming agent and an effective amount of an antimicrobial agent comprising cardamom oil.

Claim 70 is directed to a method of treatment for reducing the number or activity of bacteria in the oral cavity and requires providing an edible film composition comprising cardamom oil in an amount sufficient to kill or deactivate oral bacteria; and causing a person in need of the treatment to consume that edible film composition whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

Thus each of claims 1, 42, 62 and 70 require an edible film with an effective amount of an antimicrobial agent comprising cardamom oil. Further, claims 1, 42 and 62 require the edible film to be pullulan-free. While Pearce discloses an edible film, Pearce does not constitute prior art, and it does not disclose a pullulan-free edible film or the use of cardamom oil. While Al-Zuhair discloses cardamom oil, it does not suggest its use as a flavoring in an edible film.

As to Pearce, as pointed out during the interview and in the previous amendment, the present application claims priority to provisional application No. 60/319,498, filed on August 27, 2002. Pearce was not published until January 20, 2005. Thus Pearce cannot qualify as prior art under 35 U.S.C. § 102(a) or (b). During the interview the Examiner asserted that Pearce qualifies as prior art under 35 U.S.C. § 102(e). This position was traversed. Pearce is a continuation-in-part application, as it includes parts of the disclosures of two previously filed applications and claims priority to those applications. In addition, it claims the benefit of two previously filed provisional applications, which, like the parent applications, only disclose part of what is found in the published Pearce application.

35 U.S.C. § 102(e) only addresses the prior art effect of published applications and granted patents. It is silent on whether any earlier filed applications which did not publish or did not grant can be used as prior art. Instead, one has to look to case law interpreting 35 U.S.C. § 102(e) to determine what effect earlier filed applications that were never published or granted, but to which priority was claimed in a published/granted application, may be given. According to MPEP § 706.02(f)(1), the provisional applications to which Pearce claims priority can only be used to give Pearce an earlier effective date if the prior application “properly supports the subject matter used to make the rejection in compliance with 35 U.S.C. 112, first paragraph.” Unfortunately, the MPEP does not further explain how to determine whether the prior application “properly supports” the subject matter used to make the rejection. However, a case dealing with continuation-in-part applications decided under the earlier version of 35 U.S.C. § 102(e) helps to explain what this means.

The issue of whether a previously filed application that did not grant as a patent could be used as prior art under the former version of 35 U.S.C. § 102(e), when a continuation-in-part application was granted, was decided in the case of *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981). In that case it was held that only an application disclosing the patented invention before the addition of new matter, which disclosure is carried over into the patent, can be relied upon to give a reference disclosure the benefit of its filing date for the purpose of supporting a §§102(e)/103 rejection. 209 USPQ at 564. The court went on to state that while some of the reference patent disclosure can be traced to the parent application, “such portions of the original disclosure cannot be found “carried over” for the purpose of awarding filing dates, unless that disclosure constituted a full, clear, concise and exact description in accordance with §112, first paragraph, of the invention claimed in the reference patent, else the application could not have matured into a patent, within the Milburn §102(e) rationale, to be ‘prior art’ under §103”. 209 USPQ at 565. Thus, under the former version of 35 U.S.C. § 102(e), the 102(e) date of a granted patent could only be carried back to an earlier filed application if the granted patent claimed priority to that application, and the claims of the patent were supported as required by 35 U.S.C. § 112, first paragraph, in the parent application.

In the present case, only two of the provisional applications in the chain of applications to which Pearce claims priority were filed prior to Applicants' effective filing date: provisional applications No. 60/356,279, filed on February 11, 2002, and No. 60/368,821, filed on April 4, 2002. However, when one looks at the claims of Pearce, which are all directed to a fiber nutritional drink, and then studies the earlier filed provisional applications, it is clear that there is no support under 35 U.S.C. § 112, first paragraph, for the claims to a nutritional fiber drink of Pearce in either of the provisional applications. Therefore Pearce is not entitled to an effective prior art date under 35 U.S.C. § 102(e) before August 27, 2002, Applicants' effective filing date.

During the interview the Examiner took the position that the two provisional applications of Pearce could be used as prior art "for whatever they disclose". While Applicants believe that this broad reading of MPEP § 706.02(f)(1) is not a proper application of 35 U.S.C. § 102(e), even if this were the standard, it is clear that the presently claimed invention is not taught by, or obvious over, the disclosure in the Pearce provisional applications. This is beside the fact that the Office Action makes no effort to show how the earlier Pearce provisional applications "properly support" the subject matter used to make the rejection, as explicitly required by MPEP § 706.02(f)(1). The Pearce provisional applications contain a *pot pouri* of ideas, but as to any one idea are very sketchy in their disclosure, and it is unclear whether they provide an enabling disclosure or satisfy the best mode requirements of 35 U.S.C. § 112, first paragraph, for any specific invention, especially since they do not include any claims.

The two Pearce provisional applications have common disclosures when it comes to edible films; everything in 60/356,279 of any relevance being repeated by quotation in 60/368,821. Therefore for ease of discussion, the inadequacy of only the disclosure in 60/368,821 compared to the present claims will be discussed.

During the interview Applicants' attorney asserted that the Pearce provisional applications do not disclose a pullulan-free edible film. The Examiner pointed to the discussion on page 2 of 60/368,821 as describing numerous film forming polymers, and thus asserting that there was a disclosure of a non-pullulan edible film. However, as pointed out in the interview, the disclosure on pages 2-3 of 60/368,821 relates to a foamed edible material that is made with a film-forming polymer. The

foamed products described on page 2-3 are like commonly known packaging “peanuts” (see page 3, lines 26-27). Even though these products comprise an edible film-former polymer, they would not constitute an “edible film” as that term is used in the claims and well understood in the art.

The disclosure beginning on the last 7 lines of page 3 and all but the last 1 and ½ lines of page 4 of 60/368,821 relate to edible films. However, the only film-forming material described in this section is pullulan. There is no suggestion that the film-forming polymers listed on page 2 can be used to make an acceptable edible film. In fact, the only example uses pullulan. Hence, neither of the Pearce provisional applications disclose nor suggest a pullulan-free edible firm as required by claims 1, 42 and 62.

On pages 3 and 4, the Office Action makes reference to numerous items of disclosure in Pearce. However, as noted above, Pearce is not prior art. The Office Action has made no effort to point out any relevant disclosure in the provisional Pearce applications. Even at that, the Office Action recognizes that Pearce does not recite cardamom oil as an essential oil, nor a method of cleansing the oral cavity.

Instead the Office Action cites to Al-Zuhair as teaching that cardamom oil has antibacterial and other useful properties. The Office Action also implies that Al-Zuhair teaches that cardamom oil is an “essential oil” that would be used for flavoring purposes, and thus it would have been obvious to include cardamom oil in an edible film of Pearce. This position is traversed. The Office Action states, on page 4, that “Pearce teaches that essential oils can be applied in the edible film.” However, as noted above, Pearce is not prior art. Even considering what is suggested in the Pearce provisional applications, there is no teaching that “essential oils can be applied to edible films.” The ‘821 Pearce provisional application, when discussing edible films, states that they can include “flavor (such as strawberry flavored oil or commonly available high-flavor additives).” Page 4, lines 27-28. The example uses cinnamon oil, and the provisional application goes on to state: “The cinnamon oil in this example can, of course, be replaced by any other flavoring.” Page 4, lines 40-45. Thus, even if this provisional Pearce application somehow constituted prior art, at most it would suggest using common flavorings and high-flavor additives, rather than essential oils, in an edible film. There is nothing in Al-Zuhair that suggests that cardamom oil is a common flavoring. Thus, even though Al-Zuhair teaches several



beneficial uses of cardamom oil, it is only by impermissible hindsight reconstruction of the invention that one would consider adding cardamom oil to an edible film. Therefore claims 1, 42, 62, 70, and claims 2-22, 24-41, 43-61 and 63-69 dependent thereon, are patentable for at least the forgoing reasons over Pearce and Al-Zuhair.

Claim 71 relates to a method of oral cleansing, and requires consuming a chewing gum comprising cardamom oil present in an amount effective to be an antimicrobial agent. Neither of the provisional Pearce applications filed prior to the effective filing date of the present application disclose chewing gum, nor does Al-Zuhair. Thus, even if the provisional Pearce references are relied upon, the combination of Pearce and Al-Zuhair does not disclose the invention of claim 71. Claim 71, and claims 72-88 dependent thereon, are thus patentable over Pearce and Al-Zuhair.

Claim 90 requires a method of oral cleansing by consuming a confectionery product containing an effective amount of an antimicrobial agent wherein said antimicrobial agent is cardamom oil. As noted earlier, Applicants dispute that even the provisional Pearce applications constitute prior art. In addition, there is no suggestion of adding cardamom oil as a flavoring in any of the products disclosed in the Pearce provisional applications that could be considered to be a confectionery, and especially no suggestion to use it in an amount effective as an antimicrobial agent. Thus claim 90, and claims 91-99 dependent thereon are patentable over Pearce and Al-Zuhair.

Claim 23 was rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over Pearce in view of Al-Zuhair and further in view of U.S. Patent No. 1,056,212. This rejection is respectfully traversed. The Office Action refers to the additional reference as "Puetzer." However, as noted in response to the previous Office Action, U.S. Patent No. 1,056,212 is for a U.S. patent to Piersteien for a tube surfacing device, and not an antacid containing urea as stated in the Office Action. The Examiner in another case identified U.S. Patent No. 3,452,138 (Granatek) as possibly being the miscited reference. Granatek does disclose an antacid containing urea. However, there would be no reason from Granatek to include urea in an edible film, as required by claim 23. Furthermore, since claim 23 is ultimately depended on claim 1, and claim 1 has been shown to be patentable over the primary references, even if Granatek were used as a reference, it does not

supply the elements of claim 1 that have been shown to be missing from the provisional Pearce applications and Al-Zuhair. Thus claim 23 is patentable over Granatek, Pearce and Al-Zuhair.

Claims 71-88 were rejected in the outstanding Office Action under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,971,806 (Cherukuri) in view of Al-Zuhair. This rejection is respectfully traversed.

Claim 71 is directed to a method of oral cleansing by consuming a chewing gum comprising cardamom oil, the cardamom oil being present in an amount effective to be an antimicrobial agent. While Cherukuri discloses chewing gum, there would be no reason to combine the teachings of Al-Zuhair and Cherukuri to come up with the invention of claims 71. The Office Action implicitly recognizes that Cherukuri does not disclose cardamom oil, but refers to other items that may be included in the chewing gum of Cherukuri, such as flavor extracts derived from plants, flavor oils such as spearmint oil, and a medicament such as aspirin. However, cardamom oil is not a typical flavoring material. While it is present in some flavors, it is present at very low levels, and while Al-Zuhair states that cardamom seeds are widely used for flavoring purposes in foods, this does not mean that cardamom oil itself is a typical flavoring material. Thus there is no suggestion in Al-Zuhair to use cardamom oil as a flavoring oil, let alone as a flavoring oil in chewing gum.

Further, just because cardamom oil is listed as being useful as an anti-inflammatory agent or as an analgesic in Al-Zuhair does not mean that it is a medicament such as would be called for by Cherukuri, and not in amounts that would make it effective as an antimicrobial agent. Thus claim 71 and claims 72-88 dependent thereon are patentable over the cited references.

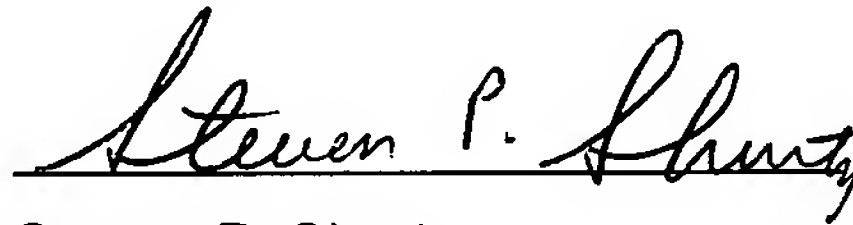
Many of the claims contain additional limitations that make them further patentable over the cited references. For example, claim 76 requires the chewing gum to comprise a food acceptable zinc or copper salt of an acid selected from the group consisting of gluconic acid, lactic acid, acetic acid, and citric acid, and combinations thereof. Claims 78 and 82 require the cardamom oil to be encapsulated. Claim 79 requires the cardamom oil to be spray dried. Claims 81 and 82 require the chewing gum to be coated, and the cardamom oil to be present in the coating. Claim 86 requires the chewing gum to further comprise a cooling agent.

The Office Action is silent on most of these features. It is believed that these limitations are not found in the provisional Pearce applications, Cherukuri or Al-Zuhair. Therefore these claims are patentable for additional reasons.

The provisional obviousness-type double patenting rejections are noted. However, since these are only provisional, and the claims in the '921 and '923 applications are not allowed, these rejections will be dealt with if needed later.

Applicants have made a novel and non-obvious contribution to the art of edible film formulations and chewing gum formulations using cardamom oil as an antibacterial agent. The claims at issue distinguish over the cited references and are in condition for allowance. Accordingly, such allowance is now earnestly requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Steven P. Shurtz", written over a horizontal line.

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